Legislative Audit Division



State of Montana

Report to the Legislature

February 2002

Performance Audit

Safeguarding Medication Stored and Administered at State Custodial Facilities

Department of Public Health and Human Services

Eastern Montana Veterans Home – Glendive
Eastmont Human Services Center – Glendive
Mental Health Nursing Care Center – Lewistown
Montana Chemical Dependency Center – Butte
Montana Developmental Center – Boulder
Montana State Hospital – Warm Springs
Montana Veterans Home – Columbia Falls

Review of controls used to safeguard medication stored in the seven DPHHS operated facilities identified a number of potential improvements. Recommendations include:

- Assure facilities store medications in physically-secured areas with restricted access.
- Implement procedures to ensure nursing staff administer medication following legal and professional guidelines.
- Ensure facilities adhere to operational and physical security regulatory requirements for administration of controlled substances.
- Implement steps to improve general medication administration.

Direct comments/inquiries to: Legislative Audit Division Room 160, State Capitol PO Box 201705 Helena MT 59620-1705

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Members of the performance audit staff hold degrees in disciplines appropriate to the audit process. Areas of expertise include business and public administration, statistics, economics, accounting, logistics, computer science, and engineering.

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LEGISLATIVE AUDIT DIVISION

Scott A. Seacat, Legislative Auditor John W. Northey, Legal Counsel



Deputy Legislative Auditors: Jim Pellegrini, Performance Audit Tori Hunthausen, IS Audit & Operations James Gillett, Financial-Compliance Audit

February 2002

The Legislative Audit Committee of the Montana State Legislature:

We conducted a performance audit of the security and administration of medication stored in Department of Public Health and Human Services facilities. The department currently operates seven facilities that house patients and residents who are either veterans, developmentally disabled or have addictive or mental disorders.

This report focuses on actions the department can take to improve medication-related operations at the seven department facilities. Recommendations address a number of areas including: physical security, administration of medication, controlled substances, and general operations.

We appreciate the cooperation and assistance of department and facility staff during the audit.

Respectfully submitted,

(Signature on File)

Scott A. Seacat Legislative Auditor

Legislative Audit Division

Performance Audit

Safeguarding Medication Stored and Administered at State Custodial Facilities

Department of Public Health and Human Services

Members of the audit staff involved in this audit were Lisa Blanford, Susan Jensen, and Mary Zednick.

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Appointed and Administrative Officials

Department of Health and Human Services

Gail Gray, Director

John Chappuis, Deputy Director

Dan Anderson, Administrator

Addictive and Mental Disorders Division

Joe Mathews, Administrator Disability Services Division

Mike Hanshew, Administrator

Senior and Long Term Care Division

Introduction

The Legislative Audit Committee requested a performance audit to assess the level of security over medication maintained in state facilities. This issue arose from LAD staff observations of less than adequate practices in the security over drug supplies at state custodial and correctional facilities. The focus of this audit was on facilities operated by the Department of Public Health and Human Services (DPHHS). There are seven such facilities in Montana:

- 1. Eastern Montana Veterans Home Glendive
- 2. Eastmont Human Services Center Glendive
- 3. Mental Health Nursing Care Center Lewistown
- 4. Montana Chemical Dependency Center Butte
- 5. Montana Developmental Center Boulder
- 6. Montana State Hospital Warm Springs
- 7. Montana Veterans Home Columbia Falls

The department is responsible for providing a full spectrum of health care services to juvenile and adult patients and residents housed in these facilities. Health care services include supplying medication. Medication includes prescriptions, over-the-counter drugs, and controlled substances as defined by the U.S. Department of Justice, Drug Enforcement Administration. The review encompassed medication handling from the time it is received at the facility – through administration of medication to patients/residents – to return of any unused medication to the pharmacy provider.

Our audit focused on controls used at each facility to physically safeguard all types of medications. A secondary objective was to review the administration of medication to patients/residents to determine if legal and professional practice guidelines are followed. Site and procedural observations were a key part of controls testing. In order to ensure our work fairly represented operations, we performed observations during a variety of staff shifts, and in a number of locations within each of the seven facilities. This allowed us to assess the entire facility. Our observations and testing results reflect an overall view of facility operations. Our visits were announced in advance to facility management and nursing staff. At

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the conclusion of audit work at each facility, we met with facility and nursing management to discuss our concerns and recommendations to improve administration and controls over medication. Facility management indicated they would begin immediate action to resolve identified concerns.

Improving Controls Over Medication

Controls over medication storage and the process used to administer medication could be improved. While some facilities had a good system of controls in place with few improvements needed, other facilities need more improvements. We believe the department can take action towards strengthening controls by clarifying what is expected of staff, and reinforcing those expectations through monitoring to ensure controls are adhered to.

Control Systems

Control systems fall into four general areas:

- 1. physical security,
- 2. administration of medication,
- controlled substances, and
- 4. general administration.

Physical Security

Laws, regulations, and facility policy require staff to store medication in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys and storage areas. Maintaining a good system of controls to ensure physical security over medications at all times involves one basic premise – all medications should be maintained under lock and key with access restricted to appropriate individuals.

We observed numerous lapses in security of medication stored in DPHHS facilities including unlocked medication storage areas, doors to medication storage rooms left open, non-functioning locks, and access to keys not adequately restricted. Controls over the physical security of medication could be improved at each of DPHHS's seven facilities. Management needs to emphasize the importance of good security procedures by periodically checking storage areas to ensure they are kept locked. In addition, efforts should focus on reviewing which individuals have access to medication storage areas and keys, and restrict this access as appropriate to their job duties. The

department needs to ensure each of its facilities adheres to federal requirements and facility policy, and have procedures in place to adequately safeguard medications at all times.

Administration of Medication

There are many guidelines and requirements related to the administration of medication including: federal regulations pharmacy-related statutes, Montana State Board of Nursing directives, DPHHS facility policies, and nursing practice and protocol. Adhering to regulations, policy and other criteria helps ensure medication is correctly administered (given) and patients/residents are not given incorrect medication or dosages, or contaminated medication. These controls are all designed to reduce the risk of medication errors. The vast number of medications that need to be administered in all DPHHS facilities, and the pressure of multiple nursing priorities complicate drug administration and can lead to medication errors.

We observed many instances where protocol related to administration of medication was not consistently followed at DPHHS facilities. We found methods staff followed to pre-set medication (prepare medication in advance of administration) do not adhere to Montana State Board of Nursing directives and nursing protocol. We observed nursing staff administer medication to patients/residents without first checking medication administration records to ensure correct medication and dose is given. Nursing staff also did not always chart medication as soon as it was given but instead waited until all patients/residents were given their medication or until the end of their shift. Some nurses charted medication prior to administering it. We also witnessed several occasions where medication was improperly disposed. We found some expired, nonlabeled, and discontinued medication in medication carts and refrigerators. In addition, although only licensed nursing staff should administer medication, one facility did periodically allow resident care aides to administer medication.

The fact that all the facilities rely primarily on licensed nursing staff to administer medication provides a solid foundation in the area of medication administration. Problems we noted are due in part to

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long-standing practices followed by some staff. In addition, staff turnover and new nursing staff can add other challenges to ensuring proper practices are followed. The department needs to ensure nursing staff are trained and understand the importance of following proper protocol when administering medication. This should include new nursing staff and contract nurses, as well as experienced nursing staff. Active monitoring by facility and nursing management to ensure protocol is followed will reinforce good practices.

Controlled Substances

Controlled substances require different handling, inventory controls, and documentation compared to other prescription drugs. This category of drugs includes narcotics, stimulants, depressants and hallucinogenics. Due to the abuse potential and risk associated with these drugs, the U.S. Department of Justice, Drug Enforcement Administration, developed regulatory requirements governing their manufacture, distribution, and dispensing. Some of these requirements impact operations at DPHHS facilities.

During our testing, we observed multiple lapses in security over controlled substances that provide opportunity for misuse or diversion of these prescription drugs. For example, nursing staff left controlled substances in unlocked and unattended medication carts. In other instances, we found unauthorized staff (locksmiths, maintenance, pharmacy technicians) had keys to storage areas. Although our testing of inventory reconciliation did not reveal any shortages of controlled substances during the time we were at the facilities, controlled substance inventory records did reveal discrepancies.

Safeguards over controlled substances could be improved at all facilities. There are several steps the department should undertake to ensure adequate controls are in place and followed. The department needs to ensure any non-functioning locks are repaired and that storage areas comply with federal regulations. In addition, particular attention must be given to ensure all documentation required for controlled substances is properly maintained and nursing staff who handle these drugs follow proper procedure in storing, administering, and accounting for them. The department should also take steps to

ensure only authorized individuals can access areas where controlled substances are kept. Active monitoring by facility management will help to ensure controls over handling, inventory, and storage of controlled substances are followed.

General Administration

During the course of audit work performed at DPHHS facilities, we identified several areas where general administration of operations could be improved. The following recommendations were made related to general operations:

- Maintain current photographs of all residents.
- Ensure facilities have equipment needed to adequately safeguard and administer medication.
- Develop a universal set of policies related to physical security and administration of medication at all DPHHS facilities.
- Develop a plan for periodic inter-facility nurse management meetings.
- Increase emphasis on supervision of nursing staff responsible for administering and safeguarding medication.

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Introduction

The Legislative Audit Committee requested a performance audit to assess the level of security over medication maintained in state facilities. This issue arose from LAD staff observations of less than adequate practices in the security over drug supplies at state custodial and correctional facilities. The focus of this audit was on facilities operated by the Department of Public Health and Human Services (DPHHS). There are seven such facilities in Montana:

- 1. Eastern Montana Veterans Home Glendive
- 2. Eastmont Human Services Center Glendive
- 3. Mental Health Nursing Care Center Lewistown
- 4. Montana Chemical Dependency Center Butte
- 5. Montana Developmental Center Boulder
- 6. Montana State Hospital Warm Springs
- 7. Montana Veterans Home Columbia Falls

The department is responsible for providing a full spectrum of health care services to juvenile and adult patients and residents housed in these facilities. Health care services include supplying medication. Medication includes prescriptions, over-the-counter drugs, and controlled substances as defined by the U.S. Department of Justice, Drug Enforcement Administration. Our audit focused on controls used at each facility to safeguard all types of medications. The review encompassed medication handling from the time it is received at the facility – through administration of medication to patients/residents – to return of any unused medication to the pharmacy provider. There are many other aspects involved in patient care. Our audit focused on security and administration of medication.

Audit Objectives and Scope

The objective of this performance audit was to evaluate the effectiveness of controls used at DPHHS facilities to ensure physical security of medication administered and maintained at each facility. A secondary objective was to review the administration of medication to patients/residents to determine if legal and professional practice guidelines are followed.

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Audit scope focused on controls over medication physically maintained at each of the facilities. We did not examine controls at off-site based pharmacies. In addition to reviewing physical security, we reviewed the process used by nursing staff at each facility to administer medication to patients/residents.

There is a category of medication called controlled substances that require different handling and documentation compared to other prescription drugs. This category of drugs includes narcotics, stimulants, depressants and hallucinogenics. Our audit scope included a review of inventory controls over these particular prescribed medications.

General administrative functions which impact storing, handling, or providing medications were also included in our audit scope. This includes things such as equipment, records, policy, and processes.

Audit Methodology

We conducted preliminary planning to gain an understanding of how DPHHS facilities administer and control medication. We interviewed department management and staff. During planning, we visited a department facility and spoke with management and staff. We toured a state-contracted pharmacy which provides medication and other services. We reviewed department and facility policies. We also obtained and reviewed pharmacy and facility management contracts applicable to each of the seven facilities.

State facilities are inspected by other entities as part of maintaining accreditation, certification, licensure, or eligibility. Six of the seven facilities are licensed health care facilities. We identified other agencies, licensing boards, or entities that conduct inspections and ascertained the extent of work done relative to examining administration of prescription drugs. The purpose of this review was threefold: (1) ensure we did not duplicate prior inspection work, (2) determine if prior concerns were resolved, and (3) identify facilities requirements.

We identified protocols, good practices, and key controls for administering and securing medication in institutional settings. We gathered information from professional licensing boards including medical, pharmaceutical, and nursing. We obtained nursing practice protocol manuals, spoke with nursing educators, and discussed controls with pharmaceutical professionals. We also used information provided by the U.S. Department of Justice, Drug Enforcement Administration, relative to safeguarding controlled substance drugs. State law, administrative rules, DPHHS policy, and individual facility policies were also reviewed.

We visited each of the seven DPHHS facilities. Visits were conducted in September and October 2001. We toured facilities and observed operations. We spoke with facility management and nursing directors. We also discussed controls and procedures with nursing and pharmacy staff, direct care aides, and employees responsible for controlling access to medication storage areas including maintenance and locksmiths.

Site and procedural observations were a key part of controls testing. In order to ensure our work fairly represented operations, we performed observations during a variety of staff shifts, and in a number of locations within each facility. This allowed us to assess the entire facility. We examined all sites where medication is stored within each facility to evaluate the physical security. Medication storage sites varied from as few as two separate sites to seventeen individual sites within a facility. We observed procedures related to administration and control of medication. These observations ranged from:

- the time a prescription is initiated,
- to receipt at the facility,
- to storage within the facility,
- to preparation prior to administering medication to patients/residents,

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- to administering medication to patients/residents,
- to handling of medication not used.

We also reviewed a variety of records maintained by facility and pharmacy staff relative to medications. This included physicians' orders and prescription ordering forms, patient charts, drug inventory records, records used to document medication given to patients/residents, logs used to document medication taken from night locker or ward stock, reporting of medication errors, patient medication review reports compiled by pharmacists, and any other records unique to each facility. We also reviewed any reports compiled by facility or pharmacy management addressing administration and control of medication.

At the conclusion of audit work at each facility, we met with facility and nursing management to discuss our concerns and recommendations to improve administration and controls over medication. Facility management indicated they would begin immediate action to resolve identified concerns.

Management Memorandum

We sent a management memorandum that addresses pharmacy notification at one DPHHS facility. Facility policy requires pharmacy staff to be notified of changes in patient status including upcoming off-site (campus) visits. Special provisions are made for patients or residents embarking on off-site visits for appointments or family visits to ensure they receive their medication during the trip.

This facility could provide more timely notice to pharmacy staff of those patients/residents scheduled for off-site visits. If the pharmacy is not notified, medication is not prepared in advance. In these instances, one of two things occurs:

- nursing staff removes medication from the patients/residents regularly packed medication and places it in an envelope or another container to be taken on the trip, or
- nursing staff does not prepare medication to be taken along.

The department should ensure facility staff follows a process which provides timely notification to the pharmacy and complies with state law.

Area For Future Review

Future audit work examining adequacy of security over prescription drugs may be warranted at other state facilities. Two other state agencies store prescriptions at their facilities. Observation by audit staff conducting financial review work in correctional facilities raised questions about the security over prescription drugs. In addition, theft of drugs occurred at a University System research facility and two staff were recently convicted in this case. Given these observations and the results of the audit of security of medication maintained at DPHHS facilities, future audit work at Department of Corrections and University System facilities may be warranted.

Introduction

This chapter presents an overview of DPHHS's health care system as it relates to providing medication services to patients or residents housed within its seven facilities. It contains general background information related to the facilities and populations served. The chapter also includes an explanation of how prescription services are obtained and provided to patients/residents.

DPHHS Facilities

DPHHS administers a wide spectrum of programs. Responsibilities include operation of state facilities housing patients/residents who are veterans, developmentally disabled, or have addictive or mental disorders. Several facilities house patients who have committed criminal offenses and have been placed there by the judicial system. The facilities are organizationally under three separate divisions within the department. Facility management reports to the department's division administrators. The following table depicts the administrative divisions, seven facilities and respective average populations during September and October 2001.

Table 1
DPHHS Facilities and Average Populations
September and October 2001

		Average
	Location	Population
Senior & Long Term Care Division		
Eastern Montana Veterans Home	Glendive	53
Montana Veterans Home	Columbia Falls	106
Disability Services Division		
Eastmont Human Services Center	Glendive	33
Montana Developmental Center	Boulder	91
Addictive & Mental Disorders Division		
Montana Chemical Dependency Center	Butte	52
Montana State Hospital	Warm Springs	183
Mental Health Nursing Care Center	Lewistown	<u>120</u>
Total Average Population		638

Source: Compiled by the Legislative Audit Division from department records.

All seven facilities provide care for patients/residents 24 hours per day. Resident care is reimbursed through a variety of sources including Veterans Administration, Medicaid, Medicare, private insurance, patients/residents who pay for their care, and DPHHS.

Senior and Long Term Care Facilities

Two state facilities provide skilled and intermediate long-term care services specifically geared to veterans and their spouses. The Montana Veterans Home is operated by the state while a contracted vendor operates the Eastern Montana Veterans Home. The homes are funded with a combination of private payments, state special cigarette tax revenue, federal funds from the Veterans Administration, and Medicare/Medicaid funds. In addition to serving residents who are physically handicapped, the homes serve residents with various forms of dementia. A unique feature of the Montana Veterans Home is the 20-bed domiciliary for veterans not needing skilled nursing care.

Disability Services Facilities

Eastmont Human Services Center and the Montana Developmental Center provide services in an institutional setting to the developmentally disabled and in some cases also physically disabled. This includes patients with mental retardation, epilepsy, autism, or other neurological conditions that require treatment similar to those required by someone with mental retardation. The population served has a developmental disability that originated before age 18 and resulted in a substantial handicap of indefinite duration. Many of the patients at both facilities require an intensive level of both nursing and daily living care, and are low functioning. A portion of the patients at Montana Developmental Center function more independently in terms of nursing and personal care assistance. Both facilities are funded with General Fund monies.

Addictive and Mental Disorders Facilities

Three facilities serve patients with addictive and mental disorders. The Montana Chemical Dependency Center serves those who are chemically dependent. About half of the population has co-occurring psychiatric disorders. Montana State Hospital is the state's only public inpatient psychiatric hospital. The hospital serves adult patients with serious and persistent mental illness. Individuals are

admitted to the hospital in one of three ways: involuntary civil commitment (70 percent), voluntary admission (5 percent), or criminal commitment (25 percent). The Mental Health Nursing Care Facility is a residential facility for the long-term care and treatment of patients who have a mental disorder and who require a level of care not available in the community, but who cannot benefit from the intensive psychiatric treatment available at Montana State Hospital. Seventy percent of admissions are patients who come from Montana State Hospital. Funding sources for Montana State Hospital and the Mental Health Nursing Care Center include General Fund and Medicaid funds. Montana Chemical Dependency Center operations are funded from alcohol tax monies.

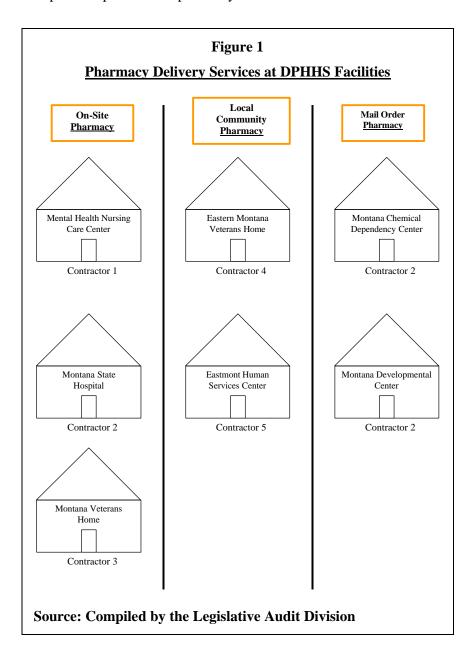
Health Care Services

The state is responsible for ensuring all patients/residents in DPHHS facilities receive the health care services they need. A wide range of health care services are required including medical, hospital, dental, mental health, vision, preventative care, and <u>pharmacy services</u>. Ongoing health care is provided on-site at each facility by department staff or contracted providers. Patients/residents who require consultations with medical specialists, or health care not readily available within department facilities, are transported off-site to community physicians, clinics, or hospitals for treatments. Skilled nursing care is provided at each facility and is available 24 hours per day. Nursing services are provided through use of registered nurses and licensed practical nurses. Direct care aides also assist patients/residents with the necessities of daily living.

Pharmacy Services

Pharmacy services are a key part of providing health care. The department relies on contracted pharmacists to provide prescription medication and pharmacy consultation services to patients/residents in its facilities. Pharmacy services are provided in three distinct ways: 1) through a pharmacy located on-site within the facility, 2) through a pharmacy located within the community, or 3) through a pharmacy located in another area of the state that mails prescriptions to the facility. There are five contracted pharmaceutical providers supplying DPHHS facilities. One contracted provider supplies prescriptions and other medications to three facilities while the other

facilities each utilize different providers. The following figure depicts the provision of pharmacy services to DPHHS facilities.



The primary duty of contracted pharmacy providers is to dispense prescriptions for patients/residents housed in DPHHS facilities. Once a prescription for medication is received, the pharmacists and their staff fill, package, label, and dispense the medication. This work is done from

within the pharmacy. The following table shows the number of prescriptions (Rxs) dispensed for each facility during June, July, and August 2001.

Table 2

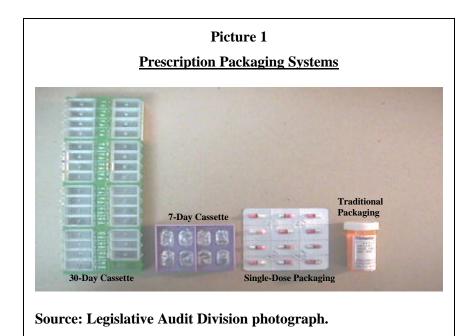
<u>Number of Prescriptions Dispensed at DPPHS Facilities</u>

June, July, and August 2001

DPHHS FACILITY	Location	Average Number of Patients	Total Rxs June	Total Rxs July	Total Rxs August
Eastern Montana Veterans Home	Glendive	53	393	368	353
Eastmont Human Services Center	Glendive	33	199	202	258
Mental Health Nursing Care Center	Lewistown	120	1116	1118	1022
Montana Chemical Dependency Center	Butte	52	204	169	136
Montana Developmental Center	Boulder	91	820	743	790
Montana State Hospital	Warm Springs	183	2403	2356	2934
Montana Veterans Home	Columbia Falls	106	397	614	538
	Totals	638	5532	5570	6031

Source: Compiled by the Legislative Audit Division from department and pharmacy contractor records.

The majority of prescriptions prepared for patients/residents in DPHHS facilities are specially packaged in a "unit dose" type system. Medications are individually packaged by patient, date, and time the dose is to be administered. With unit dose systems, medication is packaged either in thirty-day, or seven-day, or single-dose packaging. Unit dose systems have each dose individually separated. This is in contrast to the traditional packaging of a prescription in which medication is placed in a pill bottle. While unit dose systems are labor intensive for pharmacies to prepare, it is used by the health care profession to better control administration of medication and reduce the number of medication errors. These packaging systems are typically used in institutional settings. The following picture shows various medication packaging systems currently used by the seven facilities.



Once prescription packaging is completed, medication is delivered to the institution. For those facilities where the pharmacy is either located on-site, or within the local community, prescriptions are hand delivered by pharmacy staff to each facility. Medications for facilities using a non-local contracted pharmacy are mailed. The packages are tracked to ensure their delivery.

In addition to dispensing and packaging services, the contracted pharmacies also provide pharmaceutical care for residents.

Computerized records and clinical consultation are key components of this care. Additional services provided by the pharmacies include:

- Establish a drug formulary (list of drugs which physicians can prescribe) specific to the facility.
- Dispense over-the-counter medications.
- Maintain patient medication history.
- ▶ Provide consultation services and other clinical services.
- Maintain comprehensive clinical drug information.

- Check for contra-indications, drug interactions, and patient drug allergy reactions.
- Provide drug utilization services such as information by drug and prescribing physician, and number of prescriptions and doses dispensed.
- Conduct clinical pharmacy reviews of patients/residents residing in the facility.
- Supply medication administration records, narcotic control reports, and other accountability documents and reports.
- Provide a stocked supply of medication within the institution for emergency use during hours the pharmacy is closed.

Two contracted pharmacies perform additional services that extend beyond the pharmacy. These include the pharmacist physically restocking all medications kept in the facility, maintaining a detailed inventory of facility medications, and reviewing medication records maintained by nursing staff to ensure proper completion. These functions are performed to varying degrees by nursing staff in other DPHHS facilities.

Storing Medication in DPHHS Facilities

Once a prescription has been dispensed and delivered to the facility, nursing staff become responsible for it and all other medications kept in the facility. This includes ensuring medication is properly stored, safeguarded, and accounted for. All medication must be stored in locked compartments in accordance with federal and state laws, and facility policy. Generally, facilities store medication in five different types of compartments or areas: medication carts, medication rooms, refrigerators, night lockers, and controlled substance compartments.

The majority of medication kept in a facility is stored in a medication cart. This is the primary piece of equipment nursing staff work from when administering medication to patients and residents. The carts are the "workhorse" of medication administration. All DPHHS facilities use medication carts and there are anywhere from one to nine carts at each facility. The carts are mobile and can be easily pushed to patients'/residents' rooms. Most carts are set up with a specific drawer for each patient. Prescription medication for that

patient is placed in the designated drawer. Medication carts have locking mechanisms so nursing staff can lock them whenever the carts are unattended. Medication carts generally also have a storage compartment on them that separately locks. This is for storage of controlled substances such as narcotics, sedatives, stimulants or analgesics. A medication cart is shown in the following picture.

Picture 2
Medication Cart



Source: Legislative Audit Division photograph.

Another key area where medication is stored is usually referred to as a "medication room." Medication rooms are typically areas where medication that will not fit in a medication cart is kept. This could include over-sized bottles, extra medication, medication administered on an as-needed basis rather than a scheduled basis, over-the-counter medications, and medical supplies. Medication carts are often stored in these rooms when nursing staff are not working from them. If a facility does not have a separate medication room, there are cabinets that serve the same purpose.

Some medications must be refrigerated, such as vaccines, insulin, and Ativan. The facilities have separate refrigerators for storing

medication, and they either are lockable or have a compartment within that can be locked.

Another area used for storing medication is referred to as a "night locker." Medication stored in the night locker is not prescribed to a particular patient. It is for the facility's general use and functions as pharmacy stock for nursing staff to use when the pharmacy is closed or not readily available because the pharmacist is located off-site. The following picture shows a typical night locker.



Some prescription medications require special storage to ensure they are safeguarded. These drugs are referred to as controlled substances and are designated as dangerous drugs by the U.S. Department of Justice. One category of controlled substances (which has a high risk for abuse) must be stored in a separately locked and permanently affixed compartment. These compartments must be mounted so a person cannot remove it from the facility. Facilities store controlled substances in separate cabinets within a medication room or nurses station, or in a special compartment built into medication carts. The following picture illustrates an area for storing controlled substances.

Picture 4
Controlled Substance Storage Compartment



Source: Legislative Audit Division photograph.

Administering Medication to Patients/Residents

Nursing staff are responsible for giving patients and residents their medication. All patients'/residents' prescribed medications are listed on a document called a Medication Administration Record (MAR). MARs are printed by the pharmacy once a month and provided to nursing. This record is printed for each patient and contains a complete record of current medications including drug name, dosage, times to be administered, route (oral or intravenous), and special instructions. Nursing staff work from this document to administer all scheduled or unscheduled medication. Over-the-counter medication is also documented on this record. As nurses administer medication, they compare information on the MAR to the actual medication packages to ensure accuracy and reduce incidence of errors. Nursing protocol is to perform this check three times while administering each medication:

- check when you take the container from the shelf or drawer,
- check again before you place or pour the medication into a medication cup,
- check again before returning the container to the shelf or drawer.

Nurses then confirm the identity of the patient/resident and administer the medication. They document or chart which medications were administered to the patient. Documentation includes the drug administered, the dose, the date and time, the patient's reaction, if any, and the administering nurses initials. Nurses also document if the patient refuses a drug.

Most medications are administered at mealtime and bedtime. Thus, there are four key medication times each day. Depending on the facility and patient, nurses either take the medication to the patients/residents or they line up at the medication room to receive their medication.

Other Medication-Related Duties

There are several other medication-related duties performed by nursing staff. When medication is received at the facility, nursing staff check to ensure it is the correct medication and complete any documentation related to receipt. Medication is then stored in the appropriate place: the medication cart, controlled substance compartment, night locker, refrigerator, or medication room. Any medication which is discontinued, expired, or improperly labeled must be pulled from storage areas and returned to the pharmacy. Any medication a patient refuses, that is dropped on the floor, or that has a portion of a dose wasted must be documented and properly disposed of.

Controlled substances require additional documentation and special inventory procedures. Nursing staff maintains separate logs accounting for each dose administered. Controlled substances are inventoried at the end of each shift to verify the quantity on hand. Two nurses must perform reconciliation so there is a witness attesting to accuracy of records, and the type and doses of medication remaining.

Lastly, since nurses are responsible for all medication stored within the facility, they are responsible for ensuring medication is maintained in locked storage areas at all times.

Introduction

The objective of this audit was to evaluate effectiveness of controls used at DPHHS facilities to ensure medication maintained at each is physically safeguarded. A secondary objective was to evaluate the process used to administer medication to patients and residents to ensure proper protocol is followed. Our review found controls could be improved to varying degrees at each of the seven DPHHS facilities.

This chapter begins with a discussion of why controls over medication storage and administration are important and what can happen when controls do not meet or exceed established guidelines or criteria. The discussion then focuses on conditions that could contribute to control weaknesses at the seven DPHHS facilities. Specific control strengths and weaknesses are then discussed in detail along with audit recommendations for improving controls. The following sections contain charts which detail control strengths and weaknesses. Control weaknesses are denoted by a checkmark. Where there are no indicated deficiencies, strong controls are in place.

Why Strong Control Systems Over Medication Are Needed A good system of controls over medication storage and administration is important in any environment. However, based upon the nature of patients served in an institutional setting, the potential for abuse is higher, risk is greater, thus good controls are even more critical. The type of patient/resident served is a key issue. Patients and residents in DPHHS facilities have a variety of conditions that greatly increase the risk of a patient taking an unauthorized medication. For example, some patients in DPHHS facilities have been diagnosed with Pica Disorder. People with this disorder exhibit an uncontrollable urge to ingest things. Patients will swallow anything they get a hold of, including medication. DPHHS facilities also house:

- patients diagnosed with other self-injurious behaviors,
- patients who exhibit suicidal tendencies,

- patients who are kleptomaniacs,
- patients with various forms of dementia, and
- patients who are mentally unstable in general.

Another portion of the population functions at the mental capacity of children. DPHHS staff are often dealing with people who need to be shielded from access to any prescription drugs, over-the-counter medications, and medical supplies.

Another critical factor that requires a strong system of controls over medication is the type and volume of prescription medication used at many of the DPHHS facilities. Due to the client type, patients/residents are prescribed a variety of very strong medications that have the potential for abuse or addiction. Medications prescribed to patients and residents in DPHHS facilities include narcotics, depressants, stimulants, barbiturates, and anti-psychotics. The following table illustrates examples of some of these medications.

Table 3
Examples of Medication Prescribed in DPHHS Facilities

Narcotics Narcotics	Depressants	Stimulants
Uses: painkiller, anti-diarrheal.	Uses: anti-anxiety, induce sleep, relieve stress.	Uses: reduce fatigue, treat obesity attention deficit disorder.
Codeine Phosphate	Ativan	Dexedrine
Demerol	Halcion	Ritalin
Methadone	Nembutal Sodium	
Morphine Sulfate	Phenobarbital	
Oxycodone	Restoril	
Percodan	Valium	
Tylox	Xanax	
Vicodin		

Source: Compiled by the Legislative Audit Division.

Due to the potential for abuse, some medications pose a higher risk for diversion. For example, according to information published by the U.S. Department of Justice, Drug Enforcement Administration, two prescription drugs currently sought illicitly are the mood-altering drugs Oxycodone and Ritalin. Due to the popularity of these drugs on the illicit market, one 80 mg Oxycodone tablet can be sold for as much as \$80 on the street. These are just two examples. There are many other drugs used in the facilities that are mood-altering and therefore sought for illegal purposes.

The volume of drugs dispensed for patients and residents of DHPPS facilities is another factor impacting the need for proper controls. For example, at the Montana State Hospital, over 72,000 unit doses of medication are dispensed and administered to patients in a typical month. Volume of medication is a consideration at even the smallest facility, Eastmont Human Services Center. Nurses administer over 6,000 doses of medication in an average month. Volume impacts controls in two ways: (1) from a security standpoint, all these medications must be kept locked and safeguarded, and (2) from a nursing administration standpoint, all these medications need to be administered to patients/residents correctly and on time.

Operating with a good system of controls is a necessary part of ensuring proper medication-related care is provided to patients and residents, and the number of medication errors are kept to a minimum. Controls help to ensure medication is properly stored, safeguarded, and accounted for. Patient safety is increased and diversion risk reduced. In summary, a strong system of controls over medication reduces the risk to patients/residents, facility staff, and the state.

Various Causes Contribute to Lack of Proper Control

Typically, an individual audit finding and subsequent recommendation is directed at addressing the cause of a particular problem identified during the audit. However, because controls that were lacking are often "common sense" type things that need to be followed, the cause is sometimes as simple as policy or protocol just not being followed. In other cases, there are a number of things that

factor into identified control weaknesses. Due to the variety of controls tested, and number of facilities involved, we will begin by discussing the general causes of problems found during our testing at facilities. We will than discuss specific controls testing and findings, and our recommendations for improvement.

Lack of Staff Awareness and Management Inattention Contribute to Concerns

Our review showed all seven facilities had common factors, to one degree or another, which contributed to weaknesses in controls. In general, some facility staff lacked awareness of specific controls they should abide by and lacked an understanding of why particular controls were important to follow. Nursing staff turnover, new staff, and use of agency nurses (nurses that rotate working between several facilities) have aggravated the problem. Although our review of records and discussion with facility nurse management show inservice training is provided to staff at most facilities, problems continue.

Facility management inattention to daily medication nursing operations has allowed concerns to go unnoticed. Nurse management was sometimes unaware controls and policies were not adhered to within a facility. In other cases, these control deficiencies were identified by other entities that inspect the facilities, so our interviews indicated nurse management was aware of the problem. Yet, some issues continue to be problematic and unresolved.

Number of Other Factors Contribute to Problems

Other contributing causes to weak security measures over medications and nursing staff not adhering to protocol for administering medication include:

- Policy related issues, such as lack of detailed policies, or policies stored where staff did not have ready access.
- Untimely in-service training for new incoming nurses. In-service training not provided by facility nurse management to agency nurses.
- Logistical problems, such as medication inventory records being kept in a place not convenient for staff to access, malfunctioning locks on medication storage areas, or medication storage areas

simply not being large enough to accommodate supplies.

- Increased workload placed on medication nurses cause staff to rush to complete tasks.
- Management at two facilities indicated some errors are the result of being short of nursing staff and operating at minimum staffing requirements.
- Difficulty recruiting experienced nursing staff.

Controls Could Be Strengthened

The audit found controls over medication storage and the process used to administer medication could be improved. While some facilities had a good system of controls in place with few improvements needed, other facilities need more improvements. We believe the department can take positive action towards strengthening controls by clarifying what is expected of staff, and reinforcing those expectations through monitoring to ensure controls are adhered to.

The remainder of this chapter discusses the control systems we examined and the results of that testing. Our observations and testing results are not based on isolated instances; rather, they reflect an overall view of facility operations. Control systems fall into four general areas:

- (1) physical security,
- (2) administration of medication,
- (3) controlled substances, and
- (4) general administration.

Each of these areas is discussed in detail and includes recommendations that address a number of these factors and are directed at improving controls over medication administration and storage. It is important to keep in mind factors such as type of patient, number of patients or residents, and the logistical layout of a facility or campus present additional challenges to staff responsible for administering and safeguarding medication in DPHHS facilities.

Physical Security

There are state and federal laws governing proper storage of medication. Laws, regulations, and facility policy require staff to store medication in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys and storage areas. This includes drawers, cabinets, rooms, refrigerators, carts, and boxes where medication is stored. Facility certification requirements for Veterans Administration purposes, and for Medicare and Medicaid eligibility purposes, also require proper storage of and limited access to medication. Policies at each of the DPHHS facilities stipulate the same requirements. Maintaining a good system of controls to ensure physical security over medications at all times involves one basic premise - all medications should be maintained under lock and key with access restricted to appropriate individuals only. Basic physical security controls that should be followed include:

- Never leave any areas where medication is stored unlocked and unattended. This includes:
 - Medication carts
 - Medication rooms
 - Night locker stock (stock of medication for use during the time the pharmacy is closed)
 - Medication stored in refrigerators
- Restrict access to medication storage areas to appropriate individuals by:
 - Limiting which employees have keys.
 - Ensuring keys are safeguarded and not left out.
 - Ensuring all keys are accounted for.

During the audit, we examined and assessed the level of physical security over medication storage areas within DPHHS facilities. We conducted observations of all medication storage areas within a facility at varying times of day. We determined who had access to areas where medication is stored and assessed reasonableness of the access. We examined records related to what specific individuals had keys to these storage areas. Overall, we found physical security controls could be improved at DPHHS facilities. The following table

summarizes the results of our review of security controls and illustrates those areas where adequate controls are not in place.

Table 4

<u>Physical Security Controls – Testing Results</u>

DPHHS Facilities

Control	EMVH	Eastmont	MHNC	MCDC	MDC	MSH	MVH
Medication Carts Unlocked	~	~	~		V	~	V
Medication Rooms Unlocked		V				V	V
Night Locker Unlocked						V	
Medication Refrigerator Unlocked						V	
Key Assignment Not Restricted	V		~		~	V	~
Keys Left Out		~	~			~	
Inadequate Record of Keys		~	V	~	V	~	

= Control Deficiency Observed

Legend:

EMVH = Eastern MT Veterans Home MHNC = Mental Health Nursing Care Center

MCDC = MT Chemical Dependency Center

MDC = MT Developmental Center MSH = MT State Hospital

MVH = MT Veterans Home

Source: Compiled by the Legislative Audit Division.

We observed numerous lapses in security of medication stored in DPHHS facilities. Medication carts were commonly left unlocked and unattended while nursing staff left the area. The unlocked carts were out in hallways or dining areas and accessible to many individuals. We observed occasions when medication room doors were open while non-nursing staff or patients/residents were in the area, and no nurses were present. The night locker at one facility was left unlocked and unattended on multiple occasions – even after staff were reminded to keep the compartment locked. Refrigerated medication storage areas were not always locked. In addition, locks were broken on two refrigerators at one facility.

We also found all seven facilities could better control access to keys. Non-nursing staff, including maintenance, locksmiths, housekeeping, and administration, had keys to medication storage areas. Over 200 individuals were issued keys to a medication room at one facility. These individuals included a construction contractor. Records of key assignments were either lacking or outdated. We found physical access to keys was not always restricted. For example, copies of keys for medication storage areas were in locksmith shops. There were also instances keys were on a counter or hanging on a key rack that could be accessed by many individuals.

Not controlling and limiting access to medication not only jeopardizes patient safety, it places employees and the state at risk. All facilities house patients/residents who have the potential to access a medication room or cart and take things. A patient at one DPHHS facility recently obtained an unsecured medication that was not prescribed to him/her and ingested it. As a result, the patient became ill and was hospitalized. The nurse who left the medication unattended was discharged from employment as a result.

It is easier to divert drugs from storage areas that are not locked. Our observations show non-nursing staff, such as maintenance, housekeeping, and general contractors have access to rooms where medication is kept, because they were either issued keys or the areas were unlocked. In addition, any time a medication room or medication cart is left unlocked there is opportunity for visitors to the facility to have unrestricted access to medication. Theft of medication is an issue at state facilities. Within the past year, a nurse confessed to stealing medication from a DPHHS facility.

Also at issue is the fact skilled nursing facilities must comply with the requirements in the Code of Federal Regulations (CFR) to receive payment under Medicare, Medicaid or Department of Veterans Affairs programs. One requirement relates to proper storage of medication. Failure to comply could jeopardize certification and eligibility for federal funds.

Controls over the physical security of medication could be improved at each of DPHHS's seven facilities. A good control currently in place is doors, night lockers, medication carts, and refrigerators used to store medications in each of the facilities have locks. Other than a few exceptions, the locks function. Management needs to emphasize the importance of locking medication storage areas and never leaving these areas unlocked and unattended. Management should reinforce the importance of good security procedures by periodically checking storage areas to ensure they are kept locked. In addition, efforts should focus on reviewing which individuals have access to medication storage areas and keys and restrict this access as appropriate to their job duties. The department needs to ensure each of its facilities adheres to federal requirements and facility policy, and have procedures in place to adequately safeguard medications at all times.

Recommendation #1

We recommend DPHHS implement procedures to ensure facilities store all medications in locked rooms, carts, and compartments with access restricted to appropriate individuals.

Medication Administration

There are many guidelines and requirements related to the administration of medication including: CFRs, pharmacy-related statutes, Montana State Board of Nursing directives, DPHHS facility policies, and nursing practice and protocol. Adhering to regulations, policy and other criteria helps ensure medication is correctly administered (given) and patients/residents are not given incorrect medication or dosages, or contaminated medication. These controls are all designed to reduce the risk of medication errors. The vast number of medications that need to be administered in all DPHHS facilities, and the pressure of multiple nursing priorities complicate drug administration and can lead to medication errors.

Due to the importance of following proper procedures, extensive resources are committed to education specific to this area.

Textbooks discuss administration of medication and it is a frequent topic of nursing in-service training. Controls considered "safe and acceptable nursing practice" should include:

- Only licensed nursing staff should administer medication.
- Prepare medications at the time of administration. Setting up medication hours before it is to be given is never an ideal situation. (This practice is referred to as pre-setting medication.)
- Never pre-set medication into plastic or paper cups unless the medication is unit dose packaging single dose format and medication remains in the unit dose package with label attached. Cups should be labeled with the patient's name or in some way specifically identified.
- One nurse should not prepare medications for another nurse to administer.
- Prepare medications by working from the patient's medication administration record (MAR) to verify the order.
- Check the label on the medication three times before administering it to make sure the prescribed medication is given and orders followed. Compare medication label to MAR.
- Avoid touching medications. Pour liquid medications at eye level to ensure proper dosage. Shake suspensions adequately. Wash hands frequently.
- Use proper procedure to crush medication so cross-contamination does not occur.
- Properly identify the patient. Ask their name. Check wristbands or photographs.
- Remain with the patient to ensure medications are swallowed.
- Document administration of medication on the MAR before going to the next patient. Never document prior to administration. Never wait until all patients'/residents' medications are administered and then document. Do not wait until end of shift to document.
- Never administer a medication that has been dropped on the floor.

- Properly dispose of any medication which has been dropped, wasted, or which the patient refused to take. Document these occurrences on the MAR.
- Never leave medication on top of a medication cart or other accessible locations. Lock cart when unattended.
- Ensure outdated or discontinued drugs are not available for resident consumption.
- Return improperly labeled medication to the pharmacy.

During the audit, we observed the preparation and administration of medications in order to assess compliance with and adherence to proper medication administration controls. We observed a variety of nursing staff at each of the facilities. In order to ensure our observations fairly represent facility operations, we conducted them at varying times of day. We also rotated among different units or wings in the facilities to ascertain if patient type or condition impacted nursing compliance. We found administration of medication could be improved at all DPHHS facilities. The following table summarizes the results of our review of medication administration and illustrates those areas where adequate controls are not in place.

Table 5 <u>Medication Administration Testing Results</u> DPHHS Facilities

Control	EMVH	Eastmont	MHNC	MCDC	MDC	MSH	MVH
Non-nursing Staff Administer Medication	~				V		
Pre-set Medication Too Early		V		~			
Pre-set Non-Unit Dose Drugs		V		~			
Improper Pre-set of Unit Dose						V	
Do Not Use MAR To Prepare		V				V	
Improper Handling (touch, drop, do not pour at eye level, hand washing)			~		~	Ţ	
Medication Improperly Crushed					~		
Failed to Observe Patient Take Medication			V			~	
Untimely Charting: Prior to or Well After Drugs Given		V		~			
Improper Disposal of Medication				V	~	~	
Improper Charting of Refused or Wasted Drugs	~		~	V			
Medication Left Out (on top of cart or on counter)		~	~			~	~
Found Expired, Discontinued, or Improperly Labeled Drugs					~		

V= Control Deficiency Observed

Legend:

EMVH = Eastern MT Veterans Home MDC = MT Developmental Center MHNC = Mental Health Nursing Care Center MSH = MT State Hospital MCDC = MT Chemical Dependency Center MVH = MT Veterans Home

Source: Compiled by the Legislative Audit Division.

Three facilities currently pre-set medication for patients and residents. We found the methods staff followed to pre-set (get medication ready ahead of time) do not adhere to Montana State Board of Nursing directives and nursing protocol. For example, staff took medication out of its container or package, placed it in small cups, and left all the cups of medication for all the patients/residents

on top of the medication cart. This was done hours before they were to be given. In some cases, staff pre-set medication for the entire eight-hour shift at the beginning of their shift. We also observed nurses pre-set medication which should not be pre-set because it is not packaged in a unit dose (single dose) format. One facility has medication which is packaged in unit dose format; however, nurses removed the medication from its packaging when pre-setting the medication.

We observed nursing staff administer medication to patients/
residents without first checking the MAR to ensure correct
medication and dose was given. Nursing staff also did not always
chart medication as soon as it was given but instead waited until all
patients and residents were given their medication or until the end of
their shift. Some nurses charted medication prior to administering it.
We also witnessed several occasions when medication was
improperly disposed of by placing it in trashcans located in facility
hallways. We found some expired, non-labeled, and discontinued
medication in medication carts and refrigerators. In addition,
although only licensed nursing staff should administer medication,
one facility did periodically allow resident care aides to administer
medication.

According to the Centers for Medicare and Medicaid Services (CMS), medication errors can result if guidelines are not followed. Studies funded by CMS found the most common types of medication errors are: omission, administering an unauthorized (wrong) drug, wrong dosage, wrong route, wrong dosage form, untimely administration, and charting errors.

DPHHS facilities maintain documentation of medication given to patients including records of medication errors that have occurred. Our review of these records (calendar year 2001) shows instances where medication errors occurred because staff did not follow proper protocol for administering medication. For example,

Several patients in one facility were not given their medication or were given too much medication because nursing staff

administered medication without checking the MAR for proper dosage.

- A patient was given medication his/her physician had discontinued because it was contra-indicated due to a medical condition. Although the MAR indicated this change, nursing staff neglected to check the MAR and failed to remove the medication from the medication cart.
- Nursing staff missed giving multiple doses of medication to eight different patients at a facility over a one-month period.
- A patient was given an extra dose of medication because nursing staff did not record the first dose given.
- Nursing staff gave a patient medication not ordered by a physician. To complicate matters, this patient was in detoxification treatment at the time and the medication thus contra-indicated.

Discussions with and observations of facility staff also revealed other effects of not following proper protocol when administering medication. One facility we visited pre-sets all patient medications prior to administering them, and places the medications on a tray on top of the medication cart. Nursing staff stated other staff had accidentally knocked over the tray of medications on a couple of occasions and pills were scattered. In another instance, medication was left out and a patient found and ingested the medication. During our visits, we also observed several medication errors being made. In one instance, a nurse prepared medication for a patient without reading the MAR and gave the patient an incorrect dosage. In another instance, a nurse prepared medication for a patient and forgot to give it because protocol was not followed. We also observed the results of nursing staff not watching patients/residents to ensure medication is swallowed. Several patients/residents took the medication out of their mouth and dropped the pills on the floor. The nurses did not see it happen because they did not stay and observe the patient.

Staff adherence to the requirements and guidelines for proper administration of medication could be improved at the seven facilities DPHHS operates. The fact that all the facilities rely on licensed

nursing staff to administer medication provides a solid foundation in the area of medication administration. Problems we noted in this area are due in part to long-standing practices followed by some staff. In addition, staff turnover and new nursing staff can add other challenges to ensuring proper practices are followed. The department needs to ensure nursing staff are trained and understand the importance of following proper protocol when administering medication. This should include new nursing staff and agency nurses, as well as experienced nursing staff. Active monitoring by facility and nursing management to ensure protocol is followed will reinforce good practices.

Recommendation #2

We recommend DPHHS implement procedures to ensure nursing staff administers medication following legal and professional practice guidelines.

Safeguards Over Controlled Substances

Some drugs require special handling, inventory procedures, and controls. These drugs are referred to as controlled substances and are designated as dangerous drugs. Unlike other prescription drugs, controlled substances are subject to specific restrictions. The Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) contains the regulatory requirements for these substances. Controlled substances are placed into one of five schedules. Placement is based upon the substance's medicinal value, harmfulness, and potential for abuse or addiction. Schedule I is reserved for the most dangerous drugs that have no recognized medical use, while Schedule V is the classification used for the least dangerous drugs. The five schedules are:

Schedule I High potential for abuse and no recognized medical use. (Examples: heroin, LSD)

Schedule II High potential for abuse. Abuse may lead to severe psychological or physical dependence. (Examples:

morphine, methadone, oxycodone)

Schedule III Potential for abuse less than Schedules I or II.

Abuse may lead to moderate to low physical dependence or high psychological dependence.

(Examples: codeine, hydrocodone)

Schedule IV Low potential for abuse relative to drugs in Schedule

III. Limited physical dependence or psychological dependence relative to drugs in Schedule III.

(Examples: Darvon, Valium, Xanax)

Schedule V Low potential for abuse relative to drugs in Schedule

IV. Limited physical or psychological dependence relative to drugs in Schedule IV. (Example: cough

medicine with codeine)

Due to the abuse potential and risk of these drugs, the U.S. Department of Justice, Drug Enforcement Administration, developed regulatory requirements governing their manufacture, distribution, and dispensing. Some of these requirements impact operations at DPHHS facilities and must be adhered to because patients and residents in these facilities are prescribed controlled substances. The requirements include special record keeping, inventory procedures, and physical storage for Schedule II controlled substances. All facilities administering Schedule II controlled substances must follow the DEA requirements. Several facilities have also elected to apply this higher level of control to Schedule III and IV drugs.

General controls that should be in place include:

- Nursing staff should document receipt of all specifically inventoried controlled substances when received from pharmacy.
 - Verify quantity, drug type, and dosages received.
 - Check accuracy of records.
- Never leave any controlled substance unattended immediately store in appropriate location.
- Schedule II controlled substances must be stored in separately locked and permanently affixed compartments. Other controlled substances must be stored in locked compartments.
- Permit only authorized personnel to have access to keys.

- Document all specifically inventoried controlled substances administered to patients on the appropriate narcotics record.
 - Account for controlled substances on a dose-by-dose basis.
 - Document when drug is administered rather than waiting until end of shift.
- Reconcile specifically inventoried controlled substances on a daily basis to verify quantity on hand.
 - Inventory reconcile must be done by two nurses.
 - Two nurses must document and sign reconciliation.
 - Report any discrepancies to nursing supervisor and/or pharmacist.
- Destruction of specifically inventoried controlled substances must be documented and witnessed by two persons.
- Periodic supervisory review of controlled substance records.

During the audit, we observed staff, reviewed documentation, and discussed operations with facility staff and contract pharmacy staff to assess adequacy of safeguards over controlled substances. We observed nursing staff during medication administration to determine whether proper procedure was followed when handling controlled drugs. We observed inventory reconciliation of these drugs. We contacted facility maintenance personnel, including locksmiths, to identify which staff or persons had keys or access to controlled drugs within the facility. We identified all areas within each facility where controlled drugs are stored to determine if drugs were appropriately stored at all times. Overall, we found safeguards over controlled substances could be improved. While the provisions for system controls are in place, they are not always followed. The following table summarizes the results of our review of controlled substances and illustrates those areas where adequate controls are not in place.

Table 6
Safeguards Over Controlled Substances - Testing Results
DPHHS Facilities

Control	EMVH	Eastmont	MHNC	MCDC	MDC	MSH	MVH
Fail To Document Drugs Received From Pharmacy					V	V	V
No Separately Locked, Permanently Affixed Storage			V		~		
Keys and Access Not Restricted	~	~	~		~	~	~
Improper Documentation When Sign-Out Drug		V	~		~	~	
Untimely Charting Once Drugs Given			~			V	~
Medication Left Out (on top of cart or on counter)		~					V
Medication in Unlocked Cabinet	V				~	~	V
Fail to Properly Reconcile Inventory	V		~	V	~	~	
Improperly Documenting Reconciliation	~		~	~	~	V	
Destruction Not Documented and/or Witnessed						~	
No Periodic Supervisory Review	~		V	V	~	~	V

✓= Control Deficiency Observed

Legend:

EMVH = Eastern MT Veterans Home MDC = MT Developmental Center

MHNC = Mental Health Nursing Care Center
MCDC = MT Chemical Dependency Center
MSH = MT State Hospital
MVH = MT Veterans Home

Source: Compiled by the Legislative Audit Division.

We observed numerous lapses in safeguards over controlled substances including inadequate physical security, not verifying number of drugs on hand, inadequate documentation to account for all controlled substances, improper procedures for witnessing inventory and destruction of drugs, and lack of supervisory review of related procedures and documentation. We observed instances when controlled substances were stored in unlocked and unattended areas. In other cases, drugs were left out on top of a medication cart or

counter. We found keys to controlled substance storage areas are not adequately restricted and non-nursing staff has keys. In other instances, extra keys to controlled substance storage areas were accessible to many people.

Maintaining proper documentation related to controlled substances is problematic in most of the facilities. Staff often fail to verify and document the number of drugs received from the pharmacy. In addition, staff are not properly performing and documenting the reconciliation of inventory that is to be done at each shift change. We identified instances where some nurses refuse to perform this function, the inventory count is not performed and witnessed by two nurses, and drugs are not counted at each shift change. It was also common for nursing staff to improperly document when they remove a controlled substance from storage and give it to a patient. Staff either failed to record or did not record administration in a timely manner.

Controlled substances have a higher potential for abuse and, therefore, higher potential for diversion for personal or illicit use. During our testing, we observed multiple lapses in security over controlled substances that provide opportunity for misuse or diversion of these prescription drugs. For example, nursing staff left liquid methadone (Schedule II drug) in an unlocked and unattended medication cart. Another bottle of this drug was placed in a locked cabinet, however, we found unauthorized staff (locksmiths, maintenance, pharmacy technicians) have keys to this storage area. Another facility is violating the requirement that Schedule II controlled substances be kept in a separately locked permanently affixed storage compartment. This facility recently received a deficiency notice from the U.S. Department of Veterans Affairs regarding this. In another facility, liquid Ativan (Schedule III) is kept in refrigerated compartments with broken locks.

Controlled Substance Records Reveal Discrepancies

Although our testing of inventory reconciliation did not reveal any shortages of controlled substances during the time we were at the facilities, controlled substance inventory records did reveal

discrepancies. A review of records indicates controlled substances were apparently missing in four of seven facilities. For example:

- Records at one facility noted doses of Ativan and Diastat were missing and unaccounted for.
- Records at another facility showed the number of controlled substances on hand did not match the number indicated in the records. In one instance, staff was unable to reconcile controlled substances for five straight days. Records do not indicate the type or number of missing doses.
- Over a four-month period, shortages in the number of drugs on hand in one facility were identified during 33 different shifts. Missing drugs included Valium, Catapres, and Clonidine. There were also times staff found extra doses of these medications on hand.
- Documentation at one facility shows controlled substances being "wasted" by nursing staff. This can occur when only a portion of a dose is administered or if a dose is readied for administration and patient subsequently refuses it. The unused portion is considered a "wasted dose" and must be destroyed. Records show 26 instances of improperly wasted doses over a four-month period. The drugs included Ativan, Klonopin, Restoril, Valium, Xanax, and Haldol. These are anti-anxiety and anti-psychotic drugs.

Each facility's policy requires any discrepancies in the records or number of controlled substances in the inventory must be brought to the attention of a nurse supervisor, Director of Nursing, or pharmacist. We brought these records and discrepancies to the attention of nurse and facility management. They were unaware of discrepancies and could offer no explanation.

Maintaining strong controls over the handling, inventory, and storage of controlled substances is essential. Safeguards over controlled substances could be improved at all facilities. There are several steps the department should undertake to ensure adequate controls are in place and followed. The department needs to ensure any non-functioning controlled substance storage areas are repaired. The department should also ensure storage areas for Schedule II controlled substances comply with regulations. In addition, particular

attention must be given to ensure all documentation required for controlled substances is properly maintained and nursing staff who handle these drugs follow proper procedure in storing, administering, and accounting for them. The department should also take steps to ensure only authorized individuals can access areas where controlled substances are kept. Active monitoring by facility management will help to ensure controls over handling, inventory, and storage of controlled substances is followed.

Recommendation #3

We recommend DPHHS:

- A. Implement procedures to ensure facility management and staff adhere to operational and physical security regulatory requirements for the administration of controlled substances.
- B. Repair non-functioning medication storage areas and ensure Schedule II controlled substance storage areas comply with regulations.
- C. Maintain proper documentation for controlled substances at all times.
- D. Ensure only authorized individuals can access controlled substances.
- E. Require facility management to monitor staff to ensure controls over handling, inventory and storage of controlled substances are followed.

General Administration

During the course of audit work performed at DPHHS facilities, we identified several areas where general administration of operations could be improved. The following table summarizes the results of our review for the various facilities.

Table 7

<u>General Administration - Testing Results</u>

DPHHS Facilities

Control	EMVH	Eastmont	MHNC	MCDC	MDC	MSH	MVH
Resident Photos Not Current	V		V		V	V	
Updated Equipment Needed		V			V		
Inadequate or Outdated Policies	V	V		~	V		~
No Periodic Intra-Facility Nurse Management Meetings	V	V	~	V	V	~	V

= Control Deficiency Observed

Legend:

EMVH = Eastern MT Veterans Home MDC = MT Developmental Center

MHNC = Mental Health Nursing Care Center
MCDC = MT Chemical Dependency Center
MSH = MT State Hospital
MVH = MT Veterans Home

Source: Compiled by the Legislative Audit Division.

Updated Resident Photographs and Equipment Needed

Resident photographs should be available and current to aid nursing staff in administration of medication. Nursing practice and protocol guidelines require nursing staff to positively identify a patient prior to administering medication. In addition, current photographs are necessary to assist other staff or law enforcement officials in locating any patients/residents who wander from the facility. None of the facilities use patient wristbands for identification because they rely on photographs instead. All facilities generally photograph residents. However, there are missing or outdated photographs because these facilities do not routinely update them. The lack of current photographs could result in nurses making medication errors, if they are unable to correctly identify a patient. It is common for new staff to administer medication due to facilities which use contracted nurses who travel between several facilities to perform nursing duties and because of staff turnover.

Outdated equipment contributed to concerns we identified with the administration of medication in two facilities. At Eastmont, the

medication cart nursing staff uses to store and administer medication is an older model. It is too small to hold all patients' medications and does not have enough drawers to allow staff to separate each patient's medication into individual drawers. It also does not have a separate locking compartment for storage of controlled substances. As a result, staff does not comply with the Board of Nursing directives for proper pre-setting of medication and medication is placed on top of the cart and therefore not secured.

The medication carts used at the Montana Developmental Center do not have a separate locking compartment for storing controlled substances. Arrangements should be made to add this compartment to the cart. This facility also uses an old style container to crush medication. Unless the nurse washes the container between each medication that is crushed, medication is cross-contaminated. Newer vessels for crushing medication allow for medication to be placed in a paper cup and then crushed. Drug reference materials at this facility should be updated.

Facility management at both of these facilities were notified of these equipment concerns. They indicated funding constraints are partially to blame as replacing medication carts is costly. Newer model medication carts cost about \$4,000. Containers for crushing medication were not replaced as management was unaware of the problems caused.

While resident photographs and equipment related to medication administration are rather simple items they are an important part of ensuring proper administration and storage of medication. In addition, these items help minimize the risk of staff making medication errors.

Recommendation #4

We recommend DPHHS:

- A. Ensure facilities implement a process for maintaining current photographs of all residents.
- **B.** Ensure facilities have the equipment needed to adequately safeguard and administer medication.

Operational Policies

Specific program policies guide personnel in performing duties in a consistent and accurate manner. Established policies strengthen management's control over program operations and help assure continuity of operations and services as staffing changes occur. Each DPHHS facility has its own unique set of policies related to the administration of medication, physical security of medication, and handling of controlled substances. We found the level of detail and thoroughness of the facilities' policies varied greatly. While some were detailed and addressed all areas of medication administration, security, and storage, others did not. Policy manuals varied from a single page to an entire notebook. Examples of policies that were lacking include:

- Specific security measures to be taken when storing prescription medication.
- Details related to protocol nursing staff must follow when administering medication.
- Procedures to ensure regulatory requirements for controlled substances are followed.
- Stipulations regarding which classes of controlled substances are to be specifically inventoried (schedule II, III, IV, or V). The Montana State Board of Pharmacy is considering requiring a perpetual inventory of all controlled substances and some noncontrolled substances prone to abuse.
- System nursing staff is to follow when ordering re-fills or replacement (extra) medication. For example, such orders could be recorded or require nurse management approval prior to placing the order. One facility requires any nurse requests for replacement doses of schedule III, IV, and V controlled

substances be reported to the Director of Nursing as well as the pharmacist.

Policies relative to the use of automatic discontinuation of prescriptions. For example, automatically discontinue prescriptions for Schedule II controlled substances which are administered on an "as needed basis" (PRN) after a specified period of time.

Although DPHHS has instituted a department-wide policy manual, this manual relates more to general administration and personnel type issues such as hiring practices, time off, or travel. While we recognize the need for facilities to be able to adapt practices to those that best fit their needs, we also believe there is a need for a universal set of medication-related policies that all facilities must follow. These would serve as minimum guidelines for each facility. The amount and type of control problems identified during the audit points to a need for such action. Individual facility management could then add additional policies that reflect the specific needs of the facility.

Recommendation #5

We recommend DPHHS develop a universal set of policies related to physical security and administration of medication at all DPHHS facilities.

Communication Between Inter-Facility Nurse Management

Communication among the various facilities' management staff is a critical element with a decentralized organization. A process for collectively discussing strategy, operations, and on-going issues provides an effective method for identifying new or different ways of doing things. It also is a means of ensuring some consistency among facility operations.

The department schedules periodic meetings for facility administrators. This not only allows administrators an opportunity to meet with central office management, but it is also a forum for discussing intra-facility operations. Nursing management has not been afforded this same opportunity. Nurse management within a

facility routinely meet to discuss operations, policy, and other matters. However, nursing management does not have inter-facility meetings. Due to the individualized nature in which each facility operates, a forum for nursing management to share operational strategies, policies, and nursing procedures and protocols would be beneficial.

During audit work, nurse management at each of the facilities was interested in having us discuss and share specific operational procedures followed in other facilities. For example, they were interested in learning how staff in other facilities document administration of medication or how they safeguard keys. We noted several examples of topics that could be discussed at inter-facility nurse management meetings:

- Safety and security of medication.
- Topics for in-service nursing training.
- Quality assurance procedures.
- Administration of medication.
- Acceptable practice for pre-setting medication.
- Verifying and maintaining accuracy of Medication Administration Records.
- New technology.

If the department could foster inter-facility communication between nurse management, it could lead to consistent operations and more effective controls. For example, we noted each facility differs in which controlled substances they specifically inventory. We also noted most facilities do not allow medication to be pre-set, while others allow for it. Due to the decentralized organization of the department and individualized manner in which the seven facilities operate, it would be beneficial for the department to develop a plan for periodic inter-facility meetings of nurse management.

Recommendation #6

We recommend DPHHS develop a plan for periodic interfacility nurse management meetings.

Nurse Management and Supervision

A number of factors increase the risk associated with administering and storing medication in DPHHS facilities: (1) a population of patients that can be mentally unstable; (2) medication which has a high potential for abuse; (3) existence of controlled substances in the facilities; and (4) the volume of drugs dispensed. Because of these risk factors, a good system of controls over medication storage and administration is critical. Our testing and review revealed a number of weaknesses in controls used at DPHHS facilities. In addition, turnover in nursing staff, newly hired nursing staff, and use of agency nurses to fill vacant positions compounds the problems and associated risks. As a result, risk related to administrating and safeguarding medication is increased. As risk factors increase, a higher level of supervisory review is needed to ensure controls are followed and risk exposure is mitigated.

Audit work conducted at the seven DPHHS facilities showed varying levels of supervision of nursing staff. While some facilities have nursing supervisors on every shift, other facilities do not. We observed nursing directors interacting with nursing staff on a routine basis at some facilities but nursing directors had limited direct involvement in daily nursing activities at other facilities. Nurse supervisors at one facility spend the majority of their time reviewing patient charts and completing paperwork and have limited time available to supervise nurse staff. Another supervisory difference is due to nursing shortages; one facility is beginning to rely on non-nursing staff to supervise medication nurses.

The variation in the level of supervision has contributed to a number of problems. For example, while nurse management was well aware of control weaknesses and problems related to physical security of medication at some facilities, management was unaware of the extent of problems at other facilities. In addition, our control testing revealed differences between facilities in the level and adequacy of medication-related controls that were in place. This is due in part to less than adequate supervision of nursing staff.

The extent of control weaknesses, associated risks, and resulting problems point to the fact that active supervision of nurses needs to be a priority. Management needs to play a more active role in directing, controlling, and supervising nurses administering medication.

Recommendation #7

We recommend DPHHS increase the emphasis on supervision of nursing staff responsible for administering and safeguarding medication.

Department Response

DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES



JUDY MARTZ GOVERNOR GAIL GRAY, Ed.D. DIRECTOR

STATE OF MONTANA;

February 12, 2002

RECEIVED

FEB 1 4 2002

Mr. Scott A. Seacat Legislative Auditor Office of the Legislative Auditor State Capitol, Room 160 Helena, Montana 59620-1705

LEGISLATIVE AUDIT DIV.

Dear Mr. Seacat:

Attached are the Department of Public Health and Human Services responses to the recommendations made in the performance audit of Safeguarding Medication Stored and Administered at DPHHS Custodial Facilities. As a department that contains multiple facilities with differing objectives and client populations we concur in general with all recommendations made by your staff.

We appreciate the effort that has gone into your examination of DPHHS processes and policies and appreciate the thoughtfulness and professionalism displayed by your staff throughout the audit process.

Please contact me if you have questions.

Sincerely.

Director

Cc Marie Matthews
Dan Anderson
Mike Hanshew

Joe Mathews

Recommendation #1

We recommend DPHHS implement procedures to ensure facilities store all medications in locked rooms, carts, and compartments with access restricted to appropriate individuals.

Concur

DPPHS will require that all Facilities Administrators strictly enforce procedures surrounding appropriate medication controls.

Recommendation #2

We recommend DPHHS implement procedures to ensure nursing staff administers medication following legal and professional practice guidelines.

Concur

The department will ensure that effective policies are in place and are appropriate for each facility.

Recommendation #3

We recommend DPHHS:

- A. Implement procedures to ensure facility management and staff adhere to operational and physical security regulatory requirements for the administration of controlled substances.
- B. Repair non-functioning Medicaid storage areas and ensure Schedule II controlled substance storage areas comply with regulations.
- C. Maintain proper documentation for controlled substances at all times.
- D. Ensure only authorized individuals can access controlled substances.
- E. Require facility management monitor staff to ensure controls over handling, inventory and storage of controlled substances are followed.

Concur

Each facility has developed and is in the process of implementing a corrective action plan specific to their facility.

Recommendation #4

We recommend DPHHS:

- A. Ensure facilities implement a process for maintaining current photographs of all residents.
- B. Ensure facilities have the equipment needed to adequately safeguard and administer medication.

Concur

The department will ensure that all facilities have the resources and equipment required to maintain current photographs and safeguard medication.

Recommendation #5

We recommend DPHHS develop a universal set of policies related to physical security and administration of medication at all DPHHS facilities.

Concur

The department will review develop universal policies where appropriate. Individual institutions procedures with be incorporated into the agency wide policies where appropriate.

Recommendation #6

We recommend DPHHS develop a plan for periodic inter-facility nurse management meetings.

Concur

The department will develop a plan and mechanism for periodic inter-facility meetings.

Recommendation #7

We recommend DPHHS increase the emphasis on supervision of nursing staff responsible for administering and safeguarding medication.

Concur

The department will ensure the proper emphasis on supervision is maintained at all facilities.